

REMARKS/ARGUMENTS

Applicants wish to thank Examiner Sackey and Primary Examiner McKane for the courteous and helpful interview conducted on October 16, 2001. Reconsideration of this Application is respectfully requested. Upon entry of the foregoing amendment, claims 1-20 are pending in the application, with claims 1 and 2 being the independent claims. Claims 21-28 are sought to be cancelled without prejudice to or disclaimer of the subject matter therein. These changes are believed to introduce no new matter, and their entry is respectfully requested. Based on the above amendment and the following Remarks, Applicants respectfully request that the examiner reconsider all outstanding objections and rejections and they be withdrawn.

Rejection Under 35 U.S.C. § 112 ¶ 1

The Examiner has rejected claim 1 under 35 U.S.C. § 112 ¶ 1, stating that "because the specification, while being enabling for the treatment of psychotic disorders, does not reasonably provide enablement for the extraction of microparticles." Claim 1 recites a method of treating warm-blooded animals suffering from psychotic disorders comprising the administration of a pharmaceutically effective amount of sustained-release microparticles produced by a two-step process of dissolving the active agent and polymer in a solvent, and extracting the solvent. The language for the two-step process in claim 1 of the above-captioned application is identical to claim 1 of U.S. Patent No. 5,770,231 ("the '231 patent") that claims microparticles produced by the two-step process, as well as claim 4 of the '231 patent that claims the two-step process itself. The above-captioned application is a continuation of the application that issued as the '231 patent. Because the '231 patent and the above-captioned application have identical specifications, the specification of the above-captioned application necessarily provides an enabling disclosure for the two-step process. Moreover, the specification is replete with description (page 18, line 13 through page 25, line 5) and examples (1 and 2) of the two-step process. Furthermore, as noted on the Examiner Interview Summary dated October 16, 2001, "[t]he instant language is supported in the specification and in parent applications which have matured into patents." For at least the foregoing reasons, Applicants respectfully submit that the rejection under 35 U.S.C. § 112 ¶ 1 cannot properly be maintained.

Rejection Under 35 U.S.C. § 112 ¶ 2

The Examiner has rejected claims 1, 7, 9, 11, and 13 under 35 U.S.C. § 112 ¶ 2 as allegedly being indefinite based upon issues of "safety." As discussed during the interview, extraction of solvent to form microparticles does not necessarily mean that dry powder is being administered (*see*, for example, claim 7 wherein the microparticles are formulated in a liquid injection vehicle). Moreover, "safety" *per se* is not a requirement of § 112 ¶ 2. Applicants respectfully submit that claims 1, 7, 9, 11, and 13 as originally presented particularly point out and distinctly claim the subject matter that the applicants regard as their invention in a manner readily understood by one skilled in the art, as required by § 112 ¶ 2.

Obviousness-Type Double Patenting Rejection

The Examiner has rejected claims 1, 3, 5, 7, 9, 11, 13, 17, and 19 under the judicially created doctrine of obviousness-type double patenting over claims 1-22 of the '231 patent. Filed herewith is a Terminal Disclaimer to Obviate a Double Patenting Rejection Under 37 C.F.R. § 1.321(c) executed by each assignee of the above-captioned application ("Disclaimers"). Statements Under 37 C.F.R. § 3.73(b) establishing the right to act on behalf of each assignee with regard to the above-captioned application are already of record. The filing of a terminal disclaimer to obviate a rejection based on nonstatutory double patenting is not an admission of the propriety of the rejection. *Quad Environmental Technologies Corp. v. Union Sanitary District*, 946 F.2d 870 (Fed. Cir. 1991). The filing of a terminal disclaimer serves the statutory function of removing the rejection of double patenting, and raises neither a presumption nor estoppel on the merits of the rejection. *Id.*; M.P.E.P. § 804.02. Based upon filing of the Disclaimers and accompanying fee, Applicants respectfully submit that the obviousness-type double patenting rejection should be withdrawn.

Restriction Requirement

As noted on the Examiner Interview Summary, the Examiner of record will reconsider the restriction requirement to group claims 1-20 together. As discussed during the interview,

independent claims 1 and 2 are both directed to a method of treating warm blooded animals suffering from psychotic disorders, comprising the administration of sustained-release microparticles comprising risperidone or a pharmaceutically acceptable acid addition salt thereof. In claim 1, the sustained-release microparticles include a biodegradable and biocompatible polymer. In claim 2, the sustained-release microparticles include a biodegradable and biocompatible polymeric matrix. Therefore, both independent claims 1 and 2, and claims 3-20 depending directly or indirectly therefrom, are directed to methods of treating with microparticles having both a biodegradable and biocompatible polymer and risperidone. Accordingly, all of claims 1-20 are directed to methods of treating with microparticles having the characteristics of both Groups I and II. For at least this reason, Applicants respectfully submit that both Groups I and II (claims 1-20) should be examined in the present application.

Other Matters

The Examiner is requested to provide with the next written communication a copy of the initialed Form PTO-1449 that was filed on October 11, 2000.

CONCLUSION

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

Dated: October 18, 2001

Respectfully submitted,

By 

Andrea G. Reister

Registration No.: 36,253

COVINGTON & BURLING

1201 Pennsylvania Avenue, N.W.

Washington, DC 20004-2401

(202) 662-6000

Attorneys for Applicant